REMARKS

After entry of this amendment, claims 1-5, 7-9 and 26 are pending. New claim 26 has been added and finds support in the original claims 1 and 4. The new claims further narrow down the scope of the independent claim and thus, do not present any new issues that require further consideration or search. Additionally, the total number of claims is not increased in view of the cancellation of some claims. Claims 10-25 have been cancelled without prejudice or disclaimer for directing to non-elected subject matter. Claim 1 has been amended without prejudice or disclaimer and finds support *inter alia* in the original claims. Claim 1 finds further support in the specification at page 8, lines 4-5. No new matter has been added. Applicants respectfully request entry of the above claim amendment as they are believed to put the claims in condition for allowance or, alternatively, in better form for consideration on appeal. Thus, entry under 37 CFR §1.116 is correct.

Claim Rejections – 35 § 112

Claims 1-5 and 7-9 were rejected under 35 U.S.C. §112, first paragraph, for allegedly failing to comply with the written description requirement and for alleged lack of an enabling disclosure. Applicants respectfully disagree and strongly urge reconsideration and withdrawal of the rejections for the following reasons.

Written Description

The Examiner alleges that the specification fails to describe a representative number of genes encoding Δ5- and Δ8-desaturases and Δ9-elongase, and thus fail to satisfy the written description requirement. Applicants respectfully disagree.

The function of the written description requirement is to ensure that the inventors had possession of the specific subject matter **claimed**. As discussed in the Applicants' response dated November 9, 2007, the present invention relates to an improved process for the specific production of polyunsaturated fatty acids using a unique combination of known nucleotide sequences in plants, not the nucleotide sequences *per se*. Thus, the specific subject matter claimed in the present application directs to **a process**, not the nucleotide sequences that are used for practicing the claimed process.

Furthermore, the guidelines for applying the written description requirement is stated in the "Guidelines for Examination of Patent Applications Under the 35 U.S.C. § 112, 1, Written Description Requirements" 66 Fed. Reg. 1099, 1106 (Jan. 5, 2001). Example 18 of the Guideline is particularly relevant, since the claims of the present invention are drawn to methods and not to polynucleotides. The hypothetical claim in Example 18 of the Guidelines relates to a method of producing a protein and is drawn to a genus, *i.e.* any of a number of methods that can be used for expressing protein in mitochondria of the organism. As noted in the analysis of Example 18, **a particular nucleic acid is not essential to the claimed method**. Moreover, there is actual reduction to practice of a single embodiment, and there is no substantial variation within the claimed genus because there are a limited number of ways to practice the process steps. The single embodiment is found to be representative of the genus and therefore, the claim is adequately described.

Similar to Example 18, the present specification describes production of polyunsaturated fatty acids and triglycerides having an increased content of unsaturated fatty acids by introducing an oil producing plant a nucleic acid sequence encoding a Δ9-elongase, a nucleic acid sequence encoding a Δ5-desaturase, and a nucleic acid sequence encoding a Δ8-desaturase, expressing the nucleic acids, and harvesting the transgenic plant or obtaining polyunsaturated fatty acids and/or triglycerides having an increased content of unsaturated fatty acids. The specification also describes polynucleotide sequences which encode Δ5- and Δ8-desaturases and Δ9-elongase. Moreover, the present specification describes an embodiment of the method in which the nucleic acids encoding the three specified proteins are transformed into plants. Additionally, as in Example 18 of the Guidelines, the present specification provides an actual reduction to practice of the method as shown in Examples 10-11. In Example 10-11, triple transformed plants expressing Δ5- and Δ8-desaturases and Δ9-elongase were generated and the fatty acid profile and GC profile of these triple transformed plants were determined. The process used for producing the desired fatty acids is the same irrespective of the selection of polynucleotide sequences encoding the Δ5- and Δ8-desaturases and Δ9-elongase. As in Example 18 of the Guideline, the present claims are adequately described.

One skilled in the art reading the present application would clearly see possession of the claimed process irrespective of the particular sequences used, and in view of the nature of the invention, limitation of the invention to the working examples is not appropriate.

Additionally, as stated in *Capon v. Eshhar*, the descriptive text needed to meet the written description requirement varies with the nature and scope of the invention at issue, as well as the scientific and technologic knowledge already in existence. *Capon v. Eshhar*, 418 F.3d 1349, 1357 (Fed. Cir. 2005). As it will be apparent in the discussion below regarding enablement, the scientific and technological knowledge already in existence at the time of filing, together with the high level of skill in the gene isolation and expression art, one skilled artisan would immediately discern possession of all the various polynucleotides necessary to practice the claimed process.

For at least these reasons, it is submitted that the claims are in compliance with the written description requirement. Reconsideration and withdrawal of this rejection is respectfully requested.

Enablement

The Examiner further rejects the claims based on the specification allegedly not being enabling for any transgenic plant expressing any Δ5- and Δ8-desaturases and any Δ9-elongase for producing any compounds of formula I other than C20 polyunsaturated fatty acids. Applicants respectfully disagree.

The Examiner interprets the process as being enabled for "a method for **accumulate** C20 polyunsaturated fatty acids in transgenic plant." See Office Action at page 4. Applicants respectfully disagree with the Examiner's characterization. Rather, the claimed process is directed to production of compounds of formula I in a transgenic plant "**with a content of at least 1 % by weight of said compounds in reference to the total lipid content of said plant**," not merely "accumulating" C20 polyunsaturated fatty acids as alleged by the Examiner. Thus, as clearly demonstrated in Table 1 at page 50, the triple transformed plants produced not only C20 polyunsaturated fatty acids, but also various other compounds including C16 and C18 fatty acids as enumerated in Table 1. Reconsideration is respectfully requested.

The Examiner further argues that identification and isolation of the allegedly un-exemplified genes encoding Δ5- and Δ8-desaturases and Δ9-elongase is undue and unpredictable. Applicants respectfully disagree. As stated in the response dated November 9, 2007, additional genes suitable for practicing the claimed process may be readily isolated by PCR or hybridization. Other scientific tools existed and were known to one skilled in the art at the time of filing for identifying and isolating homologs of a particular gene. Conserved structure of a gene of interest is not a prerequisite requirement for such identification and isolation. For instance, a Δ9-elongase from *Euglena gracilis* was identified and isolated based solely on sequence comparison. See Damude *et al.* (US20070118929, hereinafter "Damude"). As illustrated in Damude, the Δ9-elongase of *Euglena gracilis* was identified by comparing sequences obtained from sequencing a cDNA library with the BLAST database to search for similarity with the sequence of a gene of interest. See Damude at page 26, Examples 2 and 3. Furthermore, identifying and isolating homologs of a gene by PCR or hybridization is not undue or unpredictable as alleged by the Examiner. This is further evidenced by Example 38 of Damude at page 44. As described therein, a partial cDNA fragment encoding a Δ9-elongase from *Eutreptiella* sp. CCMP389 was isolated by PCR using primers derived from conserved regions of Δ9-elongase sequences. A full-length cDNA was then obtained based on the partial cDNA fragment isolated. Because all of the techniques used in Damude to identify and isolate additional genes encoding Δ9-elongase were readily available and routinely used by one skilled in the art at the time of filing, there is no reason to doubt the operability of these techniques in identifying and isolating additional genes encoding Δ5- and Δ8-desaturases and Δ9-elongase for the use in the claimed process.

In view of the detailed description and guidance provided in the specification, as discussed in the response dated November 9, 2007, together with the skill and knowledge of the art, one skilled artisan would recognize that identifying and isolating a gene encoding Δ9-elongase and testing for its enzymatic activity is routine and not undue. The same applies to identifying and isolating a gene encoding Δ5- or Δ8-desaturase and testing for its enzymatic activity. It is therefore respectfully submitted that identifying and isolating additional genes encoding Δ5- and Δ8-desaturases and Δ9-elongase for the use in the claimed process is routine experimentation and not undue. Compare, *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988)

(routine screening of hybridomas was not "undue experimentation;" the involved experimentation can be considerable, so long as "routine"). The test for whether experimentation is "undue" is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention claimed. *Ex parte Jackson*, 217 USPQ 804, 807 (1982). The detailed guidance provided in the present specification, the skill and knowledge of the art, and the routine nature of the identification and isolation of additional genes for practicing the claimed process overcome the unpredictability alleged by the Examiner. Reconsideration and withdrawal of the rejection is respectfully requested.

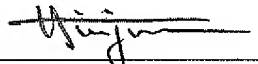
CONCLUSION

For at least the above reasons, Applicants respectfully request withdrawal of the rejections and allowance of the claims.

Applicants reserve all rights to pursue the non-elected claims and subject matter in one or more divisional applications.

This response is filed within the three-month period for response from the mailing of the Office Communication, to and including March 23, 2008. No further fees are believed due. However, if any additional fee is due, please charge our Deposit Account No. 03-2775, under Order No. 13478-00001-US from which the undersigned is authorized to draw.

Respectfully submitted,

By 

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